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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,858	03/30/2001	David W. Cannell	05725.0844-00	3869

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,858	CANNELL ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,32 and 34-150 is/are pending in the application.
- 4a) Of the above claim(s) 10-12,21-23,27,28,30,32,34,36 and 49-150 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,13-20,24-26,29,35 and 37-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/30/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Examiner acknowledges receipt of receipt of Pre-Appeal brief filed 10/05/2005. Claims 1-30, 32 and 34-150 are pending. Claims 10-12, 21-23, 27, 28, 30, 32, 34, 36 and 49-150 are withdrawn from consideration. Claims 1-9, 13-20, 24-26, 29, 35 and 37-48 are under consideration. The decision of the Pre-Appeal Conference indicated the allowability of claims 1-9, 13-20, 24-26, 29, 35 and 37-48 pending amendment to remove substituted amino polysaccharide.

Upon further review and consideration the indication of the allowability of claims 1-9, 13-20, 24-26, 29, 35 and 37-48 is withdrawn in view of the newly discovered reference(s) to Woodin, Jr. et al. (US 5,494,533), Brode et al. (US 4,767,463 or US 4,913,743) and Delrieu et al (US 5,962,015).

Rejections based on the newly cited reference(s) will follow.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-9, 13-20, 24-26, 29, 35 and 37-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicants' persuasive argument explaining why the recitation that the amino groups of the polysaccharide are unsubstituted when the C₅-C₇ saccharide unit is a polysaccharide.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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3. Claims 16, 18, 19 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is dependent on claim 1 that has the proviso that the amino group on the polysaccharide is not substituted. Claim 16 does not exclude a polysaccharide having amino group that is substituted and claim 16 appears to be requiring substituted amino group.

Claims 18 and 19 require a substitution at C1 and C2 respectively of a saccharide unit with at least one amino group. C1 or C2 of the saccharide can only be substituted with one amino group. At least one amino group indicates that the minimum is one and the maximum is undefined that can be any number greater than 1. Explanation is respectfully requested.

Claim 48 says that the composition is heat activated. However, the composition after it is applied to hair is heat activated. Thus, it is confusing to refer to the composition as heat activated since a process of --- is not claimed. Explanation is respectfully requested.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of claims 1-9, 16, 17, 19, 20, 24-26, 29, 35, 45, 46 and 47 under 35 U.S.C. 102(b) as being anticipated by Gruber (US 5,597,811) is withdrawn in view of applicants' persuasive argument that the amino group on the polysaccharide glucosamine is substituted in Gruber.

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6. Claims 1-8, 13-16, 20, 24-26, 29, 35 and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodin, Jr. et al. (US 5,494,533).

Woodin, Jr. discloses compositions and method of using said composition in personal cleansing (abstract). Exemplary compositions II-IV contain hydroxyethyl cellulose, polyquaternium and laurdimonium hydroxyethylcellulose, and other components. The polyquaternium and laurdimonium hydroxyethylcellulose are quaternary ammonium containing compounds that meet the limitation of claim 1 (a) and 2-8; while both the polyquaternium and the laurdimonium hydroxyethylcellulose meet the limitations claims 1 (a) and 2-8, the laurdimonium hydroxyethylcellulose meets the limitation of an amino polysaccharide in which the amino group is not substituted. Example III specifically has polyquaternium 24. Woodin also discloses that copolymers of saccharides and compatible synthetic monomers are employed in the cleansing composition, which meets the limitation of a compound comprising at least one C₅-C₇ saccharide units substituted with at least one amino group; the saccharides that are encompassed by the copolymers of saccharides and compatible synthetic monomers (compound) are glucose, galactose, mannose, arabinose, xylose, fucose, fructose, glucosamine, galactosamine and glucuronic acid (column 4, lines 44, 45 and 53-61). Polyquaternium 24 is present in an amount of 1.45% w/w in Example III and thus meets the limitation of claims 14 and 15. The laurdimonium hydroxyethylcellulose and glucosamine, which contain aldo-hexose amine sugars meet the limitations of claims 24-26. The composition of Woodin is packaged in container that would administer foamed compositions for topical applications (column 5, line 63 to column 7 line 26) and the composition is also formulated as foaming gels, foaming lotions and foaming scrubs and meets the limitations of claim 45. Woodin's compositions further comprise optional

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ingredients namely, conventional antibacterial agents, perfumes, dyes, preservatives, pigments, skin or hair moisturizers (column 7, line 35 to column 8 line 7); when the composition is formulated as a pharmaceutical, the composition would optionally contain pharmaceutically active agents such as analgesic, antibiotics and etc (column 8, lines 25-37). Regarding claim 29, it is noted that applicants' specification at page 7, line 20 defines the term "polymers" to include oligosaccharides. Therefore, Woodin meets the limitations of the designated claims.

7. Claims 1-9, 13, 16, 17, 20, 24-26, 29, 35, 39, 40 and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Brode et al. (US 4,913,743).

Brode discloses compositions comprising glycosaminoglycans and "certain cationic polymers" and the compositions are used in personal care or medical applications (abstract; column 2, line 45-52); Brode specifically discloses using the composition in kericare, which Brode "describes the treatment or care of keratinous material, such as hair, skin, nails or other like material, and encompasses both medical and personal care applications" (column 11, lines 22-27). According to Brode, glycosaminoglycans are polysaccharides containing disaccharide repeating units of hexosamine and hexose or hexuronic acid, the glycosaminoglycans may also contain sulfate groups (column 3, lines 20-23). The cationic polymers may be polysaccharide such as polyquaternium 4, polyquaternium 10 and polyquaternium 24 (claim 10), polyalkylenimine, poly(meth)acrylamides, polyvinyl pyrrolidones, poly (meth)acrylates, diallyl dialkyl ammonium halides and condensation polymer (column 4, lines 16-64). The glycosaminoglycans are the compounds of the claimed invention that comprises at least one C₅-C₇ saccharide unit substituted with at least one amino group. The polyquaternium meets the limitation of the claimed compound comprising at least two quaternary ammonium groups. Run

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40.1 to 40.9 contain 2.0-2.5 wt% and 0.1 wt% glycosaminoglycans (Table 1 in column 23).

The personal care composition is in the form of skin cream, bath oils, gels and etc (column 11, line 33 to column 12 line 10). Brode's composition further contains surfactants (column 12, lines 37-53), cleansers (column 12, lines 54-56), colorants, preservatives and moisturizers (column 12, lines 56-67), pH adjustment agents, emulsifiers, propellants and thickeners (column 12, line 67 to column 13 line 16). The thickeners of Brode are cellulose derivatives (column 13, lines 11-13). The cellulose derivatives listed in column 13, lines 11-13 comprise of aldo-hexose sugars and thus meets the limitation of the claimed invention further comprising additional sugar that is a polysaccharide in claim 40. Regarding claim 29, it is noted that applicants' specification at page 7, line 20 defines the term "polymers" to include oligosaccharides. Heat step is involved in the preparation of Brode's compositions (Example 2). Brode meets the limitations of the designated claims.

Brode et al. (US 4,767,463) anticipates claims 1-9, 13, 16, 17, 20, 24-26, 29, 35, 39, 40 and 45-48 under 35 U.S.C. 102(b) in the same manner as Brode et al. (US 4,913,743).

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The rejection of claims 1-9, 13-20, 24-26, 29 and 37-48 under 35 U.S.C. 103(a) as being unpatentable over Dunlop et al (US 20020102228) in view of Gruber (US 5,597,811) and further in view of Yoshihara et al. (US 5,332,581) is withdrawn in view of applicants' persuasive argument that the amino group on the polysaccharide glucosamine is substituted in Gruber.

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10. The rejection of claims 14, 15, 39-44 under 35 U.S.C. 103(a) as being unpatentable over Gruber (US 5,597,811) in view of applicants' admitted prior art is withdrawn in view of applicants' persuasive argument that the amino group on the polysaccharide glucosamine is substituted in Gruber.

11. Claims 14, 15, 37, 38 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brode et al. (US 4,913,743) in view of Raaf et al. (US 4,743,442).

Brode is discussed above. Brode discloses composition comprising glycosaminoglycans and cationic polymer. The preferred amount of the glycosaminoglycans in the composition ranges from 0.0005 wt% to about 2 wt% (column 8, line 61) as opposed to the 0.01 to 10% recited in claim 37 and the 2 wt% of Brode intersects a point in the recited range. The amount of the cationic polymer is 2.5 wt% in Run 40.3 to 40.9 and this weight percent is one of the points in the recited range of 0.01% to 10% in claims 14 and 15. Brode is silent on the presence of monosaccharides such as glucose in the composition. Raaf discloses a composition comprising glucose, alginate, polyvinylpyrrolidone and other components for use as skin care and skin protection composition (Example 8). Brode's composition is also used as a skin care composition, which is formulated in a number of forms such as lotion, cream, gel and sprays (column 11, line 33 to column 12 line 10). Thus, both compositions are used for the same general purpose. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at

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the time the invention was made to prepare the composition of Brode. One having ordinary skill in the art would have been motivated to combine the two compositions of Brode and Raaf to make a third composition that would be used for the same purpose of skin care (see *In re Kerkhoven*).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-9, 13-20, 37-40, 43, 44, 47 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-19, 26, 31-36, 38, 39, 42 and 43 of U.S. Patent No. 6,486,105. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but the examined application claim not is patentably distinct from each other because the claims are either anticipated by or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the saccharide in the examined claims is from

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C₅-C₇ while the saccharide in issued claim 1 is from C₃ to C₅ and C₅ is common to both; the compound comprising the at least two quaternary groups are the same in both the examined claims and the issued claims.

14. Claims 1-9, 13-20, 24-26, 29, 35 and 37-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 9, 10, 12-15, 19-21, 24 and 30-43 of copending Application No. 09/820,648. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but the examined application claim not is patentably distinct from each other because the claims are either anticipated by or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the film forming agent of co-pending claim 1, which is further identified as a polyquaternium in dependent claim 3 is a compound having at least two quaternary groups and the amino saccharide is the same in both the claims of the examined application and the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. Delrieu et al. (US 5,962,015) discloses lecithin-type liposomes that are stabilized with a stabilizing agent comprising quaternized polysaccharide such as laurdimonium hydroxyethylcellulose (abstract; column 2, lines 53-67, column 3, lines 5-15; columns 5 and 6).

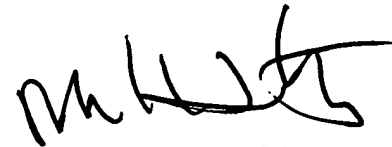
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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